Interview: Akhilesh Vijay – General Manager, Accord Healthcare – Peru

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Akhilesh Vijay came to Accord Healthcare Peru following a career at Intas Pharmaceutical in India. He urges the implementation of regulation for Biosimilars and discusses his strategy for future growth as a leading Indian generic affiliate.

How did you integrate yourself here, and what was the initial strategy? What is your opinion about your Target Market?

Intas Pharmaceuticals has been in this market for nearly ten years and initially began its operations as a distributor model. With the long term objective in mind the parent company decided to start a subsidiary operation in Peru with a legal representative in order to improve its reach and establish brands. Accord was established in Peru in 2006. From the end of 2006, Accord started commercializing products in the name of Intas. The company had presence earlier in *solidaridades*, or healthcare centers located in the provinces of Lima. We wanted to expand our reach to other potential customers by focusing on clinics, pharmacy chains and institutions, which represented a major jump. Through the participation of sales of government institutions and increasing presence in competitive horizontal markets, we have increased sales by 30 to 40 percent annually. While we face stiff competition in this market we always do have the advantage of better pricing backed by better quality.

Our strategy is to establish more therapeutic segments and grow with our biosimilar portfolio in this market. We have presence in certain therapeutic areas and are growing the same; this has given us a foothold to focus on niche markets. Biosimilars represent a significant business in Peruvian institutions. Only certain companies with sophisticated technology can offer biosimilars. Adoption of stricter norms by DIGEMID including GMP inspections will slowly wash off inferior products from the market, and pave way for high end generic products. Competition will boil down to a few players, and thereby only affordable and quality products will be made available to the patient community. As a generic company, we think that patents are generally honored in this market and are regulated by INDECOPI; but still there is hindrance in the entry of generics in certain off-patented products; this needs to change. For *Plan Esperanza* (affordable oncology treatment for all) to succeed more companies should be allowed to bring in high-quality generic products. Certain biosimilars come as lyophilized products which is cost effective. The general procurement pattern in Institution is Preference towards low cost medicines without considering the entire therapy cost. The costs incurred in purchase of syringes or diluents will add on to the total medication cost. Pre-filled syringes of good quality and fixed dose are cost-effective. I hope doctors in private clinics are more informed about the same.

Patients look for affordable medicine, and so does the government. But this will not add long-term value to patient treatment. When biosimilars are newly registered, we need to produce safety and efficacy study. As a responsible generic player Accord carries all the requisite studies. The current scenario demands DIGEMID to reach a consensus on fast tracking registration of biosimilars on the availability of such studies. Bioequivalence studies are not a requirement in Peru at the moment but they should be, and Accord can provide these as well. I frequently mention bioequivalence studies to doctors here, who ask me for the model for reference. It still is not a requirement for this market. Putting these requirements in this market will create a fairer environment. Government initiatives are good, but timelines are very long, which represent a major concern for all companies in Peru. I hope this changes so that Accord can add more products; we already have almost 40 products in the pipeline.

What is the biosimilar portfolio of Accord in Peru?

We already have registrations for two biosimilars: Erythropoetin alpha & Filgrastim in the market. We have more high-end biosimilars in the pipeline, for which we expect registration to come out soon. The major consumption of biosimilars and oncology products are in government institutions and some private clinics of groups like Auna, Rimac and Pacifico. Our biosimilar portfolio caters to therapeutic segments of oncology, ophthalmology, gynecology & orthopedics.

What is the receptiveness of MINSA in terms of what Accord as an Indian company can bring here?

In Latin America, pharmaceutical imports from India and China have often been stigmatized. However, the most FDA-approved plants outside the US are in India, including our facility. A number of Indian companies have presence in the market but most of them do business on an arm's length basis; we have our office in Peru and we represent our company to address & share information to the end users of our products. This speaks significantly of our vision as a company. We are much more direct. Accord aims at providing affordable treatment for better patient compliance. The tenders floated by DARES MINSA offers one of the biggest opportunity for sales in major hospitals of the country. The requirement is floated for products of different therapeutic segments and supply of these products requires a number of analyses. We have been successfully participating in DARES MINSA tenders and our products are widely accepted in hospitals all across the country.

How does Accord manage its Latin American network in terms of finding parallels in regulation?

Generally this has to be a case-by-case basis, as regulations in one country are not easily applicable in another. Nevertheless, FTAs with other Latin American countries and the Pacific Alliance help to a degree. Norms are becoming stricter in Peru; DIGEMID is finally doing inspections for GMP and GLP, which also vary from country to country. Creating the same norm for all countries would be beneficial for companies to invest time elsewhere, as is the case in Europe. The Pacific Alliance could standardize this, and unification in law implies unification in many other aspects.

What is the importance of Peru in Accord's LATAM structure?

We have subsidiaries in Mexico and Brazil, which are bigger markets. In Peru, stand-alone profit is what matters, but it is comparatively less than Mexico and Brazil. We anticipate more contribution from Peru with our new Product Portfolio. Peru has all the standard norms, but price deterioration and substitutions in the market at all levels have a consequence. As norms get stricter the market environment would change. This will improve the profitability of subsidiaries in the future. We will be a strong contributor to the total sales value of Latin America in the near future.

What are the most exciting products you will bring in the future?

Bringing in niche products will hold the key to growth. We have biosimilars and niche oncology pipeline to launch in the Peruvian market. Intas was one of the first companies to establish a

biopharma plant in Southeast Asia, and has been a pioneer in biosimilars, We have products with new drug delivery mechanisms which will Improve the well-being of the patient community.

What is your five-year strategy?

It depends on the vision of the parent company. Our current focus is to build the subsidiary. We will be working on launching niche products and to offer a wide range of affordable treatment options to end users.

What motivates you every day?

In recent years, the Peruvian market has become more dynamic. Every day offers a new challenge to overcome; in this scenario it is essential to be on top of all the available opportunities in the market, more so when we are targeting specialized segments. Being the face of an Indian company motivates me as It gives me an opportunity to cater to the patient needs of Peru and also to represent the country and company where I belong.

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